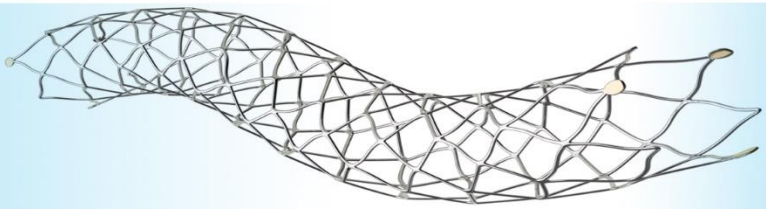
SAXOCON
Co-owned by Technical University of Denmark DTU



Safe stents and implants

A CE Mark certificate is needed in order to market a implanted medical device in the EU. This certificate verifies that the product is safe and performs as intended. The ISO 10993-1 standard prescribes a process for evaluating and testing the biological safety of a medical device product that includes physico-chemical, morphological, and topographical characterization of materials. SAXOCON provides you with everything you need to plan, test, and document compliance with regulatory requirements including:

- A Biological Evaluation Plan to describe and justify your test strategy
- Robust selection of construction materials
- Physico-chemical, morphological and topographical tests according to methods and principles in ISO/TS 10993-19
- The selection of appropriate laboratories, review of protocols, and monitoring of biological tests according to the requirements in the ISO 10993-series
- Assistance with scientific advisory meetings with regulatory bodies
- A toxicological risk assessment of results

Why choose us?

SAXOCON services for medical device manufacturers give you access to:

- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals
- Extensive experience in state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on proprietary information obtained from our world-wide network of materials suppliers
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles all necessary documentation for the approval of your product in a Biological Evaluation Report.

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